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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,437	12/17/2001	Stephen A. Johnston	5171-00041	2358

7590 10/02/2008

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ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
10/02/2008	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/023,437
Filing Date: December 17, 2001
Appellant(s): JOHNSTON ET AL.

JOHNSTON ET AL.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 9, 2008 appealing from the Office action mailed January 28, 2008.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of invention contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The Appellant's statement of the issues in the brief is correct.

(7) Claims Appendix

Appellant's copy of the appealed claims contained in the appendix is correct.

(8) Evidence Relied Upon

Sato et al *(Science, Vol. 273, July 19, 1996, p.352-354).*

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

I. Claims 92, 94-95 and 104-121 are rejected under 35 U.S.C. 101 because they are directed to non-statutory subject matter. Independent 92 in particular, reads on a product that exists in nature because it recite "...administering a *Chlamydia psittaci* antigen...". This rejection may be obviated, if the claims are amended to an "isolated or purified" *Chlamydia psittaci* antigen.

II. Claims 92, 94-95 and 104-121 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of immunizing an animal comprising the step of administering a genetic vaccine comprising pooled DNA clones or full-length genes and/or fragments from *Chlamydia psittaci* (see Example 8 and Example 9) and a protein vaccine comprising a pool of full-length proteins and/or a pool of protein fragments from *Chlamydia psittaci* (see Example 9) in an amount effective to induce an immune response against *Chlamydia psittaci;* does not provide enablement for a method of immunizing an animal comprising the step of administering a single *Chlamydia psittaci* antigen to an animal in an amount effective to induce an immune response against *Chlamydia psittaci;* wherein the *Chlamydia psittaci* antigen comprises the amino acid sequence as set forth as SEQ ID Nos. 7, 9, 11 and 13 (examined sequences).

The claimed invention is directed to a method of immunizing an animal comprising administering to the animal a single isolated *Chlamydia psittaci* antigen. The instant specification has not enabled the claimed invention. The specification has shown enablement for immunizing cattle with a pool of 14 DNA genes. See Example 8 and Table 4 of the instant specification. The specification has also shown enablement for a genetic vaccine comprising a pool of five protective full-length genes and/or gene fragments isolated in the gene screening process. The instant specification has further shown enablement for a protein vaccine which comprises full-length *Chlamydia psittaci* proteins and/or protein fragments. See Example 9 of the specification. It should be noted that it is unclear as to whether the genetic vaccine disclosed in Example 9 comprises a pool of full-length genes or gene fragments or a combination thereof. It is also unclear as to whether the protein vaccine disclosed in Example 9 comprises a pool of full-length proteins or protein fragments or a combination thereof. However, the genetic and protein vaccines disclosed in Example 9 appear to aid in fertility. It should be noted that the vaccine compositions used to vaccinate the animals in the specification comprise pools of genes or proteins. Thus, one of skill in the art cannot ascertain whether one single gene or protein or a combination of genes or proteins provide the protection described in Examples 8 and 9 of the instant specification. It is unclear as to *which specific genes* and *which specific proteins* are present in the vaccine compositions of Examples 8 and 9 of the instant specification. Further, if it is one single gene or protein that provided protection and fertility specifically, which single gene or protein is it?

As stated above, the instant specification has only provided one example, Example 8, that relates specifically to vaccination of animals. However, this example immunizes the animals with a *pool of 14 gene clones*. Thus, the specification discloses a method of immunizing animals comprising a pooled DNA vaccine and *not a method of immunizing an animal comprising administering a Chlamydia psittaci protein vaccine comprising administering* ***one single*** *Chlamydia psittaci* antigen as recited in the instant claims. One of skill in the art would not reasonably conclude that a DNA vaccine and a protein vaccine would behave in the same manner when administered to an animal. It should be noted that the claimed method is directed to immunizing an animal with a single *Chlamydia psittaci* antigen in an amount that is effective in inducing an immune response to the administered *Chlamydia* antigen. Sato et al *(Science, Vol. 273, July 19, 1996, p.352-354)* teach that DNA vaccines do not necessarily induce an immune response to the encoded antigen (see the Abstract).

Therefore, given the lack of success in the art, the lack of working examples commensurate in scope to the claimed invention and the unpredictability of the generation of a immune reaction to a specific antigen, the specification, as filed, does not provide enablement for a method of immunizing an animal comprising administering a *Chlamydia psittaci* protein vaccine comprising administering ***one single*** *Chlamydia psittaci* antigen.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the

presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification for a method of immunizing an animal comprising administering a *Chlamydia psittaci* protein vaccine comprising administering one single *Chlamydia psittaci* in an amount effective to induce an immune response against *Chlamydia psittaci*, the amino acid sequence as set forth in SEQ ID NOs. 7, 9, 11 and 13) and 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use the claimed invention in a manner reasonable in correlation with the scope of the claims. Without proper guidance, experimentation is undue.

In view of all of the above, the unpredictably in the art, the lack of enablement and the lack of guidance in the instant specification, one of skill in the art would require guidance in order to make and use the claimed invention commensurate in scope with the claimed invention. Therefore, Applicant has failed to satisfy the requirements of 35 U.S.C. 112 first paragraph.

III. Claims 104-106 rejected under 35 U.S.C. 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 104 depends from independent claim 92. Claims 105 depends from claim 94 which depends from independent claim 92. Claim 106 depends from independent claim 92. Claims 104-106 recite "...wherein the step of preparing...". There is *not* a step of preparing in claim 92. Correction is required.

(10) Response to Arguments

I. Response to Arguments Traversing the Rejection of claims 92, 94-95 and 104-121 are rejected under 35 U.S.C. 101 because they are directed to non-statutory subject matter.

Appellants Specific Arguments Restated

I. Appellant urges they are willing to make the suggested corrections to obviate the rejection under 35 U.S.C. 101.

Examiner's Response to Appellant's Arguments

I. In response to Appellant's arguments filed July 9, 2008, the preceding rejection will be maintained until amendments are made to the current claims under appeal.

Appellants Specific Arguments Restated

II. Appellant urges that the purpose of the requirement that a specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. Appellant refers to MPEP 2141.

A) Appellant urges that *In re Wands* sets out the factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether undue experimentation is necessary.

Appellant urges that that the Examiner should always look for enabled, allowable subject matter and communicate to the Appellant at the earliest point in prosecution.

B) Appellant provides a lengthy assessment of what they believe is the prosecution history for this application.

C) Appellant's arguments that actually address the outstanding rejection under 35 U.S.C. 112 first paragraph are as follows:

Appellant urges that prior art antibiotic treatment for *Chlamydia* is not practical and conventional vaccines are inconsistent. Appellant urges that a vaccine for prevention of the disease in animals is desirable.

Appellant urges that the application includes working and prophetic examples. Appellant urges that they used expression library immunization (ELI) for identified

candidates in the present application. Appellant urges that to identify the particular sequences or fragments that were advantageous, the inventors conducted a series of experiments with mice as detailed in Figure 5. Appellant refers to the Declaration submitted by Dr. Kaltenboeck. Appellant urges that pages 70-72 of the instant specification show clones that contained Chlamydia psittaci DNA inserts that coded for open reading frames of more than 50 amino acids were identified in three rounds of screening. Appellant refers to Figure 3 and page 70 of the instant specification. Appellant urges that fourteen gene fragments were identified and those gene fragments were tested in the experiment of Figure 5 of the application on mice. Appellant urges that four controls were used. Appellant urges that the results indicate that genetic immunization with CP4#1 to 5 achieved protection from Chlamydia psittaci better than what is achievable from a natural low dose vaccination. Appellant urges that from the experiment of Figure 5, particular gene fragments that were effective to induce an immune response against Chlamydia psittaci were identified. Appellant urges that the most highly protective gene identified was Gene No.1 of Figure 5 which corresponds to CP4#1 in Table 2 in Figure 6 of the present application. Appellant urges that CP4#1 was sequenced and is represented by SEQ ID NOs. 6-9 wherein Sequence No.6 is the original DNA gene fragment, Sequence ID No:7 is the polypeptide fragment corresponding to the gene fragment of No.6, Sequence ID NO.8 is the full-length DNA gene that includes the gene fragment of SEQ ID NO.6 and Sequence ID No.9 is the full-length polypeptide sequence of SEQ ID No.8.

Appellant urges that because Figure 5, demonstrates a specific method of immunizing an animal including the step of administrating a *Chlamydia psittaci* antigen to an animal in an amount effective to induce an immune response against *Chlamydia psittaci* and wherein the antigen comprises the sequence set forth in SEQ ID NO:7, Appellants believe the method of the present invention is enabling.

Appellant urges that the state of the art of making and using antigenic peptide is well known using PCR techniques for amplifying a coding sequence of the DNA of a fragment, cloning these into expression vectors, expressing the protein in any recombinant protein expression system and then purifying the protein. Appellant urges that SEQ ID NO:7 is the amino acid sequence of the most highly protective gene fragment identified in Examples 1-4, in Figure 5 and demonstrates the efficacy of that particular gene fragment in conferring protection and because it is routine to convert back and forth between an amino acid sequence and the nucleic acid sequence that encodes it.

Appellant urges that the level of skill in the art is high. Appellant refers to Tang et al, Babiuk and Ellis to support their position.

Appellant urges that the level of predictability of identifying whether a particular sequence or gene is efficacious in immunizing is high, as methods and protocols for determining whether or not a gene or fragment thereof provides an immune response is known, Appellant urges that while the amount of experimentation to practice the full scope of the claimed invention might have been extensive, it is routine.

Appellant urges that the instant specification, the cited references and pages 90-98 of the present application provide an abundant amount of direction to provide a method of immunizing an animal with the sequences that are identified. Appellant urges that the working examples demonstrate that amino acid sequences of SEQ ID Nos.7, 9, 11, 13, 27 and 29 all confer immunity. Appellant urges that claims for fragments and full-length polynucleotide and polypeptide sequences of protective genes are identified in the examples, particularly in example 5.

Examiner's Response to Appellant's Arguments

II. A) Appellant's arguments filed July 9, 2008 have been fully considered but they are not persuasive. It is the Examiner's position that Appellant is not enabled for the claimed method.

MPEP 2164.01(a) discloses:

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention *without undue experimentation*. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The determination that *"undue experimentation"* would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. *In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404*. These factual considerations are discussed more fully in MPEP § 2164.08 (scope or breadth of the claims), § 2164.05(a) (nature of the invention and state of the prior art), § 2164.05(b) (level of one of ordinary skill), § 2164.03 (level of predictability in the art and amount of direction provided by the inventor), § 2164.02 (the existence of working examples) and

§ 2164.06 (quantity of experimentation needed to make or use the invention based on the content of the disclosure).

MPEP 2164.01(b) discloses:

As long as the specification discloses at *least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied.* In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. 112. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), cert. denied, 484 U.S. 954 (1987). Naturally, for unstable and transitory chemical intermediates, the "how to make" requirement does not require that the applicant teach how to make the claimed product in stable, permanent or isolatable form. In re Breslow, 616 F.2d 516, 521, 205 USPQ 221, 226 (CCPA 1980).

A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court in In re Ghiron, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a The Court in In re Ghiron, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. In re Howarth, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

Based on MPEP requirements set forth in MPEP 2164, Appellant's claims are not enabled for a method of immunizing an animal in an amount effective to induce an immune response against *Chlamydia psittaci*, wherein the *Chlamydia psittaci* antigen comprises the amino acid or polypeptide sequence as set forth in SEQ ID NOs. 7, 9, 11 or 13 (sequences examined in the application).

To address Appellant's arguments regarding MPEP 2141, the Examiner has addressed the Wands factors in the rejection of the claims under 35 U.S.C. 112 first paragraph.

B) To address Appellant's summary of the prosecution history of this application, it should be noted that a prosecution history is not a requirement in an appeal brief. Appellant should note that MPEP 2106 discloses that:

The claims define the property rights provided by a patent, and *thus require careful scrutiny. The goal of claim analysis is to identify the boundaries of the protection sought by the applicant and to understand how the claims relate to and define what the applicant has indicated is the invention. USPTO personnel must first determine the scope of a claim by thoroughly analyzing the language of the claim before determining if the claim complies with each statutory requirement for patentability.* See In re Hiniker Co., 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998) ("[T]he name of the game is the claim."). USPTO personnel should begin claim analysis by identifying and evaluating each claim limitation. For processes, the claim limitations will define steps or acts to be performed. For products, the claim limitations will define discrete physical structures or materials. Product claims are claims that are directed to either machines, manufactures or compositions of matter.

USPTO personnel are to correlate each claim limitation to all portions of the disclosure that describe the claim limitation. This is to be done in all cases, regardless

of whether the claimed invention is defined using means or step plus function language. The correlation step will ensure that USPTO personnel correctly interpret each claim limitation. The subject matter of a properly construed claim is defined by the terms that limit its scope. It is this subject matter that must be examined. As a general matter, the grammar and intended meaning of terms used in a claim will dictate whether the language limits the claim scope. Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation. The following are examples of language that may raise a question as to the limiting effect of the language in a claim:

USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily). In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("*During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow.... The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed.... An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.*").

Based on the MPEP 2106, the Examiner has *determined the scope of the claimed invention by thoroughly analyzing the language of the claims before determining if the claims comply with each statutory requirement for patentability*. In the instant case, the claimed invention *does not* comply with 35 U.S.C. 112 first paragraph.

C. Appellant claims, a method of immunizing an animal in an amount effective to induce an immune response against *Chlamydia psittaci*, wherein the *Chlamydia psittaci* antigen comprises the amino acid or polypeptide sequence as set forth in SEQ ID NOs. 7, 9, 11 and 13 (sequences examined in the application). Thus, the claimed invention is directed to a method of immunizing an animal comprising administering to the animal a *single isolated Chlamydia psittaci antigen* (e.g. the amino acid sequence set forth in SEQ ID NOs. 7, 9, 11 or 13 (examined sequences). It is the Examiner's position that the instant specification has *not enabled* the claimed invention.

The instant specification teaches that the ability of an antigen to produce an immune response may be employed in vaccination or antibody preparation techniques. See page 4. The specification teaches that the present invention provides compositions and methods for the immunization of vertebrate animals, including humans, against infections using nucleic acid sequences and polypeptides elucidated by screening *Chlamydia psittaci*. See page 16. The specification also teaches that the compositions and methods of the invention will be useful for immunization against *Chlamydia psittaci* bacterial infections and other infections and disease states. See page 16. The specification further teaches method for screening and identifying *Chlamydia* genes that confer protection against infection. See page 16. Thus, the claimed method encompasses immunizing an animal comprising the step of administering a single *Chlamydia psittaci* antigen in an amount effective to induce "a protective" immune response against *Chlamydia psittaci* bacterial infections and other infections and disease states.

The specification has shown enablement for immunizing cattle with a *pool of 14 genes* (DNA not protein as recited in the claimed method). See Example 8 and Table 4 of the instant specification. The specification has also shown enablement for a genetic vaccine comprising a *pool of five protective full-length genes and/or gene fragments* isolated in the gene screening process. However, animals were immunized with a pool of genes or gene fragments and *not individual or single Chlamydia psittaci antigens as recited in the claims.*

The instant specification has further shown enablement for a protein vaccine which comprises full-length *Chlamydia psittaci* proteins and/or protein fragments. See Example 9 of the specification. It should be noted that it is unclear as whether the genetic vaccine disclosed in Example 9 comprises a pool of full-length genes or gene fragments or a combination thereof. It is also unclear as to whether the protein vaccine disclosed in Example 9 comprises a pool of full-length proteins or protein fragments or a combination thereof. However, the genetic and protein vaccines disclosed in Example 9 appear to aid in fertility. It is unclear as to *which specific genes* and *which specific proteins* are present in the vaccine compositions of Examples 8 and 9 of the instant specification. Further, if it's one single gene or one single protein that provided protection and reduced infertility, which single gene or single protein is it?

It should be noted that Example 8 states:

"The inventors will test different combinations of those genes which have found to be individually protective, as well as combinations with CP4 #11". "Both the original fragments and their full-length versions can be tested, both nucleic acid segments and protein". "Once the combinations have been verified in mice or other small mammals, those combinations showing the most promise will be tested in cows". "After immunization, the cows will be challenged with *Chlamydia psittaci*, either by direct challenge at insemination or infection by herd-mates". See page 83 of the instant specification.

The instant specification teaches that Appellants are not enabled for their claimed method since Example 8 states that the claimed method had not yet been performed.

It should be noted that the vaccine compositions used to vaccinate the animals in the specification comprise *gene products or pools of genes or pools of proteins*. Thus, one of skill in the art would *not agree* that immunizing an animal with gene products or pools of genes from *Chlamydia psittaci* antigen would provide enablement for *immunizing an animal* with a single *Chlamydia psittaci* antigen. One of skill in the art *would not agree* that immunizing an animal with pooled or multiple *Chlamydia psittaci* antigens would provide enablement for immunizing an animal with a single *Chlamydia psittaci antigen*.

To address Appellant's comment's regarding Figure 5, it should be noted that this figure merely discloses the results of protection assays of testing 14 single gene fragments in round 4 of screening (not antigen or protein as recited in the claimed method) provide some level of protection when administered to mice. The instant

specification fails to disclose *a method of immunizing an animal comprising administering a Chlamydia psittaci* antigen in an amount effective to induce an immune response against *Chlamydia psittaci comprising administering* ***one single*** *Chlamydia psittaci* antigen as recited in the instant claims.

Appellant asserts that because Figure 5, demonstrates a specific method of immunizing animals with a *Chlamydia psittaci* gene fragments to an animal in an amount effective to induce an immune response against *Chlamydia psittaci*, they believe that they are enabled for the method.

The Examiner strongly disagrees with this assertion. As stated above, the assays performed and illustrated in Figure 5 are a result of immunizing mice with gene fragments, (DNA) and not protein. The art is unpredictable regarding immunizing an animal with DNA verses immunizing an animal with protein. Sato et al *(Science, Vol. 273, July 19, 1996, p.352-354)* teach that vaccination with naked DNA elicits cellular and humoral immune response that have T helper cell type 1 bias. However, *plasmid vectors expressing large amounts of gene product do not necessarily induce immune responses to the encoded antigens* (see the Abstract). The cited art teaches that DNA and proteins react differently when administered to animals. Therefore, administering a gene or gene product to an animal is not the same as administering a protein to that same animal.

To address Appellant's comments regarding examples 1-4 of the instant specification, these examples merely disclose how Appellant started with over 82,000 clones and arrives at 14 clones, that were further characterized.

To address Appellant's comment regarding, using well known PCR techniques, while it is true that these techniques are well known in the art. It should be noted that the claimed invention is directed to a method of immunizing an animal comprising the step of administering a *Chlamydia psittaci* antigen to an animal in an amount effective to induce an immune response against *Chlamydia psittaci* comprising administering **one single** *Chlamydia psittaci* antigen. At most, regarding enablement for administering *Chlamydia psittaci* antigens to animals, Appellant has shown enablement for a method of immunizing an animal comprising administering a *Chlamydia psittaci* protein vaccine comprising *a pool of Chlamydia psittaci antigens.*

To address Appellant's comments regarding the Declaration submitted by Dr. Kaltenboeck, this declaration was submitted to address the Examiner's questions about the correlation between Figure 5, the CP4 numbers and the SEQ ID Nos. disclosed in the instant specification. This declaration fails to provide data regarding, immunizing an animal with **one single** *Chlamydia psittaci* antigen.

To address Appellant's comments regarding, cite references, Tang et al, Babiuk and Ellis, it should be noted that Ellis is a review article disclosing the new technologies in vaccine development. It should be noted that Ellis teach that clinical efficacy for DNA vaccines is yet to be shown. See Ellis, page 1602, 4.1 Purified DNA section. Additionally, Babiuk teaches that it is not possible to quantitate the level of protein produced *in vivo* following plasmid introduction. Babiuk also teaches other concerns regarding polynucleotide vaccination is that plasmids introduced into host cells possibly precipitate aberrant cell division due to mutations, chromosome alterations or

rearrangements. Babiuk further teaches that polynucleotide vaccination may raise anti-DNA antibodies following DNA immunization. See Babiuk, page 1593. Finally, Tang et al teach that biolistic instrument can be used for genetic immunization. However, Tang et al teach that injection with a plasmid did not produce an immune response. Thus, this reference teach that based on the type of genetic immunization used an immune response may or may not be achieved. Based on the teaching of the *prior art cited by Appellants*, the state of the art is unpredictable regarding DNA immunization. Thus, Applicant's assertion that "it is routine to convert back and forth between an amino acid sequence and the nucleic acid sequence that encodes it" and their assertion that immunizing with gene products demonstrated in Examples 1-4 and in Figure 5 demonstrate the efficacy of that particular gene fragment in conferring protection is not well founded. Since the *prior art cited by Appellants* teaches that DNA immunization is unpredictable.

As stated above, a key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available *only after extensive screening*. In the instant case, Appellant started with over 82,000 gene clones. Appellant performed extensive screening to arrive at 14 gene clones that were possibly protective. After, further screening, Appellant arrived at five clones that appeared to be protective. However, the instant specification falls short of enabling the claimed invention because the instant

specification only discloses immunizing an animal comprising administering *gene products* or *a pool of gene products or a pool of antigens*. Based on the instant specification and what is known in the art *Chlamydia psittaci* regarding *Chlamydia psittaci* antigens, one skilled in the art would not reasonably conclude that immunizing animals with *gene products* or a vaccine comprising multiple proteins and/or protein fragments would provide enablement for the claimed invention. Since the claimed method is directed to *immunizing animals with a single Chlamydia psittaci antigen*. Since the instant specification discloses a method of immunizing animals with gene products or pooled vaccines comprising multiple proteins or genes the skilled artisan would not be able to ascertain which *Chlamydia psittaci* antigen or antigen(s) is providing the immunization against *Chlamydia psittaci* or protective immunity if the *Chlamydia psittaci* antigens are not administered and evaluated individually in the animals.

Therefore, given the lack of success in the art, the lack of working examples commensurate in scope with the claimed invention and the unpredictability of the generation of an immune reaction to a specific antigen, the specification, as filed, does not provide enablement for a method of immunizing an animal comprising the step of administering a *Chlamydia psittaci* antigen to an animal in an amount effective to induce an immune response against *Chlamydia psittaci* comprising administering ***one single*** *Chlamydia psittaci* antigen. It should be remembered that *Chlamydia psittaci* antigens as set forth in SEQ ID NOs. 7, 9, 11 and 13 were examined in this application.

III. Response to Arguments Traversing the Rejection of claims 104-106 rejected under 35 U.S.C. 112 second paragraph.

Appellants Specific Arguments Restated

III. Appellant urges they are willing to make the suggested corrections to obviate the rejection under 35 U.S.C. 112, second paragraph.

Examiner's Response to Appellant's Arguments

III. In response to Appellant's arguments filed July 9, 2008, the preceding rejection will be maintained until amendments are made to the current claims under appeal.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Examiner's Answer Conclusion

For the above reasons, it is believed that the Examiner should be affirmed.

Respectfully submitted,

/Vanessa L. Ford/

Patent Examiner, Art Unit 1645

September 25, 2008

/Shanon A. Foley/
Supervisory Patent Examiner, Art Unit 1645

/Bruce Campell/
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